DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46531

Re: K093803
Trade/Device Name: Bio-Modular® Reverse Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: October 14, 2010
Received: October 15, 2010

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of October 19, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K093803

OCT 19 2010

510(k) Number (if known): K093803

Device Name: Bio-Modular® Reverse Shoulder

Indications For Use:
The Bio-Modular® Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Bio-Modular® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joretta Z for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093803

BIOMET MANUFACTURING CORP.

K093803

OCT 19 2010

510(k) Summary

Preparation Date: October 19, 2010

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Bio-Modular® Reverse Shoulder

Common Name: Shoulder Prosthesis

Classification Name: Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis (21 CFR 888.3660)
Shoulder joint metal/polymer, semi-constrained, uncemented prosthesis (21 CFR 888.3670)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Comprehensive® Reverse Shoulder (Biomet) - K080642

Device Description: The Bio-Modular® Reverse Shoulder is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional total shoulder replacement, a reverse shoulder employs a ball for articulation on the glenoid side of the joint and a polyethylene bearing surface on the humeral side of the joint. The components may be used as a primary procedure or during the revision of a failed shoulder prosthesis.

For a reverse shoulder application, a Glenosphere Baseplate with a Glenosphere is implanted into the glenoid side of the joint. The Glenoid Baseplate is attached to the natural bone with the use of a Central Screw and Peripheral Screws. A Humeral Tray with a Humeral Bearing is attached to a Bio-Modular® Humeral Stem to complete the humeral side of the joint. The use of a standard Bio-Modular® humeral component provides the surgeon with the option of leaving a well-fixed humeral stem from a previous total or hemi-shoulder surgery in place while still being able to convert the shoulder to a reverse configuration. It also would facilitate the conversion of a reverse configured shoulder to a hemi-shoulder in the future if the need were to arise.

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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K093803

Intended Use: Biomet Bio-Modular® Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Bio-Modular® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Summary of Technologies: The Bio-Modular® Reverse Shoulder has similar technologies as the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing (fatigue testing) and engineering analysis (separation loads, change of face angle, assembly/disassembly and range of motion) were performed to determine substantial equivalence. The results indicated that the device was functional within its intended use. Magnetic Resonance Imaging (MRI) studies have been conducted.

Clinical Testing: None provided as a basis for substantial equivalence.